

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION**

**NATUROPATHIC LABORATORIES
INTERNATIONAL, INC.,**

Plaintiff,

vs.

**DERMAL RESEARCH
LABORATORIES, INC.,**

Defendant.

Case No. 02-604-CV-W-GAF

CLAIM CONSTRUCTION OF '984 PATENT

Now before the Court are the arguments propounded by each side regarding how terms and phrases used in the disputed patent, Patent No. 5,888,984 ("the '984 Patent") should be construed and interpreted. Patent infringement disputes are resolved using a two-step process. The present Order involves the first step and delineates the meaning of terms in the '984 Patent, as a matter of law.

As previously indicated, infringement disputes are resolved by working through two steps. Kegel Co. v. AMF Bowling, Inc., 127 F.3d 1420, 1425 (Fed. Cir. 1997). In the first step, the court interprets the meaning and the scope of the words and phrases used in the patent claims. Kegel, 127 F.3d at 1425. As the Supreme Court has stated, the construction of a claim is a legal matter and is "exclusively within the province of the court." Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996). In the second step, the jury, or other finder of fact, evaluates whether the disputed device infringes upon the patent as interpreted by the court. Kegel, 127 F.3d at 1425.

While there are many sources upon which a court may rely when construing a claim, the court should be guided first, and foremost, by intrinsic evidence of record, such as the language of the claim

itself. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). A court should endeavor to give terms contained in a patent claim their “plain ordinary and accustomed meaning[.]” Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). This presumption in favor of the plain meaning will be overcome if the patentee clearly sets forth a definition of a given term within the claim that differs from the term’s ordinary meaning. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002). The court should also look to other intrinsic evidence including the specification and the prosecution history. Tegal Corp. v. Tokyo Electron Am., Inc., 257 F.3d 1331, 1342 (Fed. Cir. 2001). Intrinsic evidence, as listed above, has been described as “the most significant source of the legally operative meaning of claim language.” Kegel, 127 F.3d at 1426 (quoting Vitronics Corp., 90 F.3d at 1582). A court may also use evidence that is not part of the claim, the specification or the prosecution history, but only in limited circumstances. Kegel, 127 F.3d at 1426.

Extrinsic evidence, such as expert testimony, may be used by the court to construe a claim. Vitronics Corp., 90 F.3d at 1582. However, extrinsic evidence may only be utilized if the intrinsic evidence is not dispositive or is ambiguous. Id. Additionally, extrinsic evidence cannot be used to contradict or vary the claim language. Id. at 1584. This limitation applies not only to expert testimony, but also to evidence of how prior art would construe disputed terms. Id.

Guided by the above directions, the Court concludes that the following definitions of terms and phrases are appropriate. In each case, the Court finds that the definition is more accurately supported by the intrinsic evidence, specifically the language of the claims themselves and the prosecution history. Each definition shall carry throughout the entirety of the claim unless otherwise so stated.

Claim 1

“A topical pharmaceutical composition which comprises as an active ingredient a

pharmacologically effective amount of at least one low purity or cosmetic grade complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides and glycosaminoglycans, and at least one essential oil in an amount effective to allow penetration of the dermis of mammals by the complex carbohydrate.”

“Pharmaceutical composition” means a medicinal drug that is used in the treatment or prevention of a disease or as a component of a medication.

“Topical” means applied to a localized area of the body or to the surface of a body part.

The transitional term “comprising,” which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

“Drug” means a substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication.

“Active” means producing an intended action or effect: active ingredients.

“Pharmacology effective” mean an amount that is medically effective.

“Low purity” means less than pure.

“Cosmetic grade” means material of lower cost, yet compatible with human use.

“Complex carbohydrates” means a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate, dermatan sulfate, keratan sulfate and acemannan, for example.

“Essential oil” means any of a large class of volatile odoriferous oils of vegetable origin that give plants their characteristic odors and often other properties, that are obtained from various parts of the plants (as flowers, leaves, or bark) by steam distillation, expression, or extraction, that are usually mixtures of compounds (as aldehydes or esters), and that are used often in the form of essences

in perfumes, flavorings, and pharmaceutical preparations.

“Amount effective” means a quantity that produces a result.

“Allow penetration of the dermis of mammals by the complex carbohydrate” means the combination of the complex carbohydrate and the essential oil produces a treatment effect by the complex carbohydrate. That treatment effect is pain relief.

“Dermis” means the sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels.

Claim 2

“The pharmaceutical composition according to Claim 1, wherein said complex carbohydrate is a polysaccharide.”

“Polysaccharide” includes glycosaminoglycans and mannans.

Claim 4

“The pharmaceutical composition according to Claim 1, wherein said essential oil is natural or synthetic.”

“Essential oil is natural or synthetic” means that the essential oil can be naturally created or manufactured.

Claim 6

“The pharmaceutical composition according to Claim 2 wherein said complex carbohydrate is selected from the group consisting of a glycosaminoglycan and a mannan.”

“Glycosaminoglycans” means hyaluronic acid, chondroitin sulfates A, B, and C, heparin sulfate, heparin, keratan sulfate, dermatan sulfate, etc.

“Mannan” means mannose-based polysaccharides normally extracted from plants.

Claim 7

“The pharmaceutical composition according to Claim 6, wherein said glycosaminoglycan is selected from the group consisting of hyaluronic acid, heparin, heparin sulfate, chondroitin sulfate, polysulfated glycosaminoglycan and keratan sulfate.”

“Glycosaminoglycans is selected from the group consisting of hyaluronic acid, heparin, heparin sulfate, chondroitin sulfate, polysulfated glycosaminoglycan and keratan sulfate” means the glycosaminoglycan is chosen only from those listed in this group.

Claim 12

“The pharmaceutical composition according to Claim 1, wherein said complex carbohydrate comprises a mixture of molecular weight ranges.”

“Molecular weight” means the sum of the atomic weights of all the atoms in a molecule.

“Mixture” means a composition of two or more substances that are not chemically combined with each other and are capable of being separated.

Claim 16

“The pharmaceutical composition according to Claim 1, wherein said complex carbohydrate is in a concentration ranging from 0.1% to 99% wt/vol and said essential oil is in a concentration from 0.5% to 20% vol/vol.”

“Said complex carbohydrate is in a concentration ranging from 0.1% to 99% wt/vol” means that the complex carbohydrate is present in any amount from 0.1 to 99% wt/vol.

“Said essential oil is in a concentration from 0.5% to 20% vol/vol” means that the essential oil is present in any amount from 0.5% to 20% vol/vol.

Claim 27

“A method of inhibiting the inflammatory process by introducing a pharmacologically effective

amount of at least one low purity or cosmetic grade complex carbohydrate selected from the group consisting of oligosaccharides sialylated oligosaccharides, polysaccharides and glycosaminoglycans, which is biospecific for the adhesion cascade and blocks the binding of leucocytes to the epithelium during migration and extravasation of leucocytes to a site of trauma.”

“Inhibit” means to decrease, limit, or block an action or function.

“Inflammatory” means accompanied by or tending to cause inflammation.

“Inflammation” means a local response to cellular injury that is marked by capillary dilatation, leukocytic infiltration, redness, heat, and pain and that serves as a mechanism initiating the elimination of noxious agents and of damaged tissue.

“Biospecific” means doing something biologically in a specific way.

“Adhesion cascade” means a mechanism for causing inflammation resulting in pain by “block[ing] the binding of leucocytes to the epithelium during migration and extravasation of leucocytes to a site of trauma” which means the complex carbohydrate blocks the white blood cells (leucocytes) from binding to the inside wall of the blood vessel (epithelium) preventing the blood cell from traveling to the site of trauma and flow into the tissue to create the swelling (extravasation of the leucocytes).

Claim 28

“A method for inhibiting inflammation which comprises: providing a pharmacologically effective amount of at least one low purity or cosmetic grade complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides and glycosaminoglycans, and which inhibits the adhesion cascade so as to inhibit binding of leucocytes to epithelium, mixing said compound with an essential oil to obtain a mixture, and applying said mixture to a site in need of treatment to inhibit inflammation.”

“Mix” means to combine or blend into one mass or mixture; to create or form by combining ingredients.

“Mixture” means a composition of two or more substances that are not chemically combined with each other and are capable of being separated.

Claim 29

“The pharmaceutical composition according to Claim 4, wherein said natural or synthetic essential oil is Menthol.”

Menthol is listed in the specification as an essential oil.

Claim 31

“The pharmaceutical composition according to Claim 1, wherein said at least one complex carbohydrate has a molecular weight in the range of from 1,000 to less than 50,000 daltons.”

Claim 32

“The pharmaceutical composition according to Claim 1, wherein said at least one complex carbohydrate has a molecular weight in the range of from 100,000 to 500,000 daltons.”

Claim 33

“The pharmaceutical composition according to Claim 1, wherein said at least one complex carbohydrate has a molecular weight in the range of greater than 750,000 daltons.”

Claim 35

“A topical pharmaceutical composition consisting essentially of: as an active ingredient a pharmacologically effective amount of at least one low purity or cosmetic grade complex carbohydrate selected from the group consisting of oligosaccharides, sialylated oligosaccharides, polysaccharides and glycosaminoglycans, and at least one essential oil in an amount effective to allow penetration of the dermis of mammals by the complex carbohydrate.”

“Consisting essentially of” typically limits the scope of the claim or limitation to the specified materials as well as those materials that do not materially affect the basic and novel characteristics of the claimed invention.

Claim 36

“The pharmaceutical composition according to claim 1, which is in the form of an emulsion, suspension, solution, cream or ointment.”

“Emulsion” means a suspension of small globules of one liquid in a second liquid with which the first will not mix.

“Solution” means a homogeneous mixture of two or more substances, which may be solids, liquids, gases, or a combination of these.

“Suspension” means a system in which microscopically visible particles are dispersed throughout a less dense liquid or gas from which they are easily filtered but not easily settled because of system viscosity or molecular interactions.

“Cream” means a usually emulsified medicinal or cosmetic preparation.

“Ointment” means a highly viscous or semisolid substance used on the skin as a cosmetic, emollient, or medicament.

Claim 37

“A composition for topically treating inflammation, pain or itching, comprising: a pharmaceutically effective amount of a low purity or cosmetic grade glycosaminoglycan or mannan in combination with an essential oil present in an amount effective to allow penetration of the dermis of mammals by the glycosaminoglycan or mannan.”

For “topically treating inflammation, pain or itching,” see the claim construction provided for similar terms or phrases used in limitations of Claims 1, 27, and 28.

“Composition” means the combining of distinct parts or elements to form a whole.

“Pharmaceutically effective” means medically effective, which is distinguished from a cosmetic.

“Combine” means to join (two or more substances) to make a single substance, such as a chemical compound.

Claim 41

“A method of treating pain and inflammation comprising: topically applying a pharmaceutical composition consisting essentially of a low purity or cosmetic grade glycosaminoglycan or mannan combined with an essential oil present in an amount effective to allow penetration of the dermis of mammals by the glycosaminoglycan or mannan.”

Claim 43

“The topical pharmaceutical composition of Claim 1, wherein said composition is a pain-relieving composition.”

“Pain relieving composition” means the composition treats pain.

Claim 46

“The topical pharmaceutical composition of Claim 35, wherein said composition is a pain-relieving composition.”

Claim 47

“The composition of Claim 1, wherein the low purity or cosmetic grade complex carbohydrate contains up to 5% by wt. contaminants.”

“Complex carbohydrate contains up to 5% by wt. contaminants” means that no more than 5% by weight of the complex carbohydrate are contaminants.

Claim 49

“A method of treatment of inflammation, pain or itching which comprises topically applying to the skin of a mammal the composition of Claim 1.”

Claim 52

“The pharmaceutical composition of Claim 1, wherein the essential oil is present in a concentration of between 0.5% to 20% vol/vol.”

“The essential oil is present in a concentration of between 0.5% to 20% vol/vol” means the essential oil in the composition is present in a concentration of between 0.5% to 20% vol/vol.

Claim 54

“The pharmaceutical composition of Claim 28, wherein the essential oil is present in a concentration of between 0.5% to 20% vol/vol.”

Claim 55

“The pharmaceutical composition of Claim 35, wherein the essential oil is present in a concentration of between 0.5% to 20% vol/vol.”

Claim 59

“The topical pharmaceutical composition of Claim 1, wherein said at least one low purity or cosmetic grade complex carbohydrate has a molecular weight in the range of from 1,000 to less than 50,000 daltons, from 100,000 to 500,000 daltons, or greater than 750,000 daltons.”

“Complex carbohydrate has a molecular weight in the range of from 1,000 to less than 50,000 daltons, from 100,000 to 500,000 daltons, or greater than 750,000 daltons” means that the molecular weight range of the complex carbohydrate is within that recited therein.

Claim 65

“The topical pharmaceutical composition of Claim 35, wherein said at least one low purity or cosmetic grade complex carbohydrate has a molecular weight in the range of from 1,000 to less than

50,000 daltons, from 100,000 to 500,000 daltons, or greater than 750,000 daltons.”

IT IS SO ORDERED.

/s/ Gary A. Fenner
GARY A. FENNER, JUDGE
United States District Court

DATED: **January 23, 2004**

Hitchner Sandra

From: Weiner, Marc
Sent: Tuesday, October 11, 2005 8:08 AM
To: Hitchner Sandra
Subject: FW: Markman Claim Construction

Sandra

Please print this off...this being the PDF file

thanks

From: Kkbhgb@aol.com [mailto:Kkbhgb@aol.com]
Sent: Monday, October 10, 2005 11:07 PM
To: Weiner, Marc
Subject: Markman Claim Construction

Marc,

Attached is the Markman Claim Construction. Note that the definitions are on page 3.

Best Regards,
Karen K. Brown, Ph.D.
Dermal Research Laboratories, Inc.

10/11/2005